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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,122	02/14/2002	Dale Clifford	6005.019	8896
32361	7590	04/01/2004		
GREENBERG TRAUIG, LLP 885 3RD AVENUE NEW YORK, NY 10022			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER /1
DATE MAILED: 04/01/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/076,122

Applicant(s)

CLIFFORD ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-14,16-19 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-14,16,23 and 25-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,6-14,16-19 and 23-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant response/amendment filed January 2, 2004 has necessitated a restriction requirement.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-4, 6-14, 16, 23, and 25-38, drawn to a vertebral implant, classified in class 623, subclass 17.11.
- II. Claims 17-19 and 24, drawn to a method of providing an orthopedic implant, classified in class 606, subclass 151.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using may be used with a different product than the product in group I. (a vertebral implant), for instance a plate, wrap, or fastener for surrounding a long bone.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group II. is not required for Group I., restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew B. Tropper (Registration No. 37,457) on March 23, 2004 a provisional election was made without traverse to prosecute the invention of Group I., claims 1, 3-4, 6-14, 16, 23, and 25-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-19 and 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Drawings***

The drawings corrections were received on January 2, 2004. These drawings are approved.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6-13, 16, 23, 25-35, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Veldhuizen et al. (USPN 6,656,178 B1). See figure 1e and respective portions of the specification. Referring to claims 1, 4, 25, and 27, Veldhuizen discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra comprising a foraminous, corrugated biocompatible material formed into a sleeve (1), the implant having a first end (2), second end (3), and a length dimension extending therebetween, the first and second ends being open (fig. 1e), wherein the first open end (2) is adapted to contact a first vertebrae and the second open end (3) is adapted to contact the second vertebrae , and the implant bears a load between the first and second vertebrae (col.12, lines 34-38), wherein the biocompatible material has a thickness between about 0.5mm and 3.0mm (col.12, lines 19-21), and is titanium (the implant comprises titanium and alloys thereof, col.4, lines 5-10; col.12, lines 8-10).

Referring to claims 3, 6, 7, 26, 28, and 29, Veldhuizen discloses the implant to have a plurality of lobes and depressions (waves) having four and six (seen in fig. 1e).

Referring to claims 8, 9, 11, 12, 30, 31, 33, and 34, Veldhuizen discloses the implant constructed of a foraminous (openings 6; col.12, lines 50-52) corrugated (waves) loop or sheet (fig. 1e), having a substantially circular or elliptical shape (col.6, lines 3-5).

Referring to claims 10 and 32, Veldhuizen discloses an implant comprised of an intersecting network of landed regions (biocompatible material) that define a plurality of

openings (6) in the network, wherein the openings (6) are dispersed among the landed regions (fig.3, 6; col.7, lines 1-4).

Referring to claims 13, 23, 35, and 38, Veldhuizen discloses an implant that surrounds bone graft material or bone growth promoting material (col.7, lines 52-53).

Referring to claims 16 and 37, Veldhuizen discloses the sleeve to be an inner sleeve, and having further an outer sleeve surrounding the inner sleeve (fig.10, 11c; col.7, lines 45-48).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (USPN 5,609,637). Referring to claim 1, Biedermann discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra (fig.4-6) comprising a foraminous (3), corrugated (6) biocompatible material formed into a sleeve (1), the implant having a first end, second end, and a length dimension extending therebetween (fig.1-3), the first and second ends being open, wherein the first open end is adapted to contact a first vertebrae and the second open end is adapted to contact the second vertebrae, and the implant bears a load between the first and second vertebrae (fig.4-6). Biedermann has shown a sleeve (1) having a thickness (see figures, hollow, col.1, lines 26-28), however is silent to mention exact dimensions for such thickness. It would have been an obvious matter of design choice to have a thickness of between about 0.5mm and 3.0mm, since such a modification would have involved a

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mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Referring to claim 4, Biedermann discloses the biocompatible material to be titanium (col.2, lines 6-7).

Referring to claims 3, 6, 7, Biedermann discloses the implant to have a plurality of lobes and depressions (6) having four and six (fig.1-3).

Referring to claims 8, 9, 11, 12, Biedermann discloses the implant constructed of a foraminous (3) corrugated (6, col.1, lines 37-40) loop or sheet (1), having a substantially circular or elliptical shape (col.1, lines 26-29).

Referring to claim 10, Biedermann discloses an implant comprised of an intersecting network of landed regions (titanium sheet 1) that define a plurality of openings (3) in the network, wherein the openings (3) are dispersed among the landed regions (see figures).

Claims 1, 3-4, 6-11, 14, 16, 25-33, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schar et al. (USPN 6,176,881 B1). Referring to claims 1, 4, 25, and 27, Schar discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra (col.1, lines 4-5) comprising a foraminous (30, fig.1), corrugated (5, fig.1, 7) biocompatible material formed into a sleeve (1), the implant having a first end, second end, and a length dimension extending therebetween (fig.1, 7), the first and second ends being open, wherein the first open end is adapted to contact a first vertebrae and the second open end is adapted to contact the second vertebrae, and the implant bears a load between the first and second vertebrae (col.1, lines 4-5). Schar discloses the implant to be a load bearing

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biocompatible material and (rigid material, col.1, lines 34-35) having a thickness (fig.1, 6, 7), however is silent to mention any specific materials, or dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant out of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. It also would have been an obvious matter of design choice to have a thickness of between about 0.5mm and 3.0mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Referring to claims 3, 6, 7, 26, 28, and 29, Schar discloses the implant to have a plurality of lobes and depressions (5, seen in fig.1, 3, 7) having four and six.

Referring to claims 8, 9, 11, 30, 31, and 33, Schar discloses the implant constructed of a foraminous (30) corrugated (5) loop or sheet (1), having a substantially circular shape (fig.6).

Referring to claims 10 and 32, Schar discloses an implant comprised of an intersecting network of landed regions (sleeve material, 1) that define a plurality of openings (30) in the network, wherein the openings (30) are dispersed among the landed regions (fig.1).

Referring to claims 16 and 37, Schar discloses the sleeve to be an inner sleeve (1), and having further an outer sleeve (2) surrounding the inner sleeve (fig.6).

Referring to claims 14 and 36, Schar discloses the sleeve (1) to have a plurality of openings (30, or openings seen in fig.6 where 25 and 26 protrude therethrough), the implant having a cerclage (24 +25+26) passing through the openings and secured to the sleeve (see fig.6).



***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Cheryl Miller". The signature is fluid and cursive, with the first name "Cheryl" written in a larger, more prominent script than the last name "Miller".

Cheryl Miller

BRUCE SNOW  
PRIMARY EXAMINER